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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,495	02/20/2002	Walter Herman Maria Louis Luyten	JAB-1526	3238

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EXAMINER	
ANGELL, JON E	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/069,495	LUYTEN, WALTER HERMAN MARIA LOUIS
	Examiner	Art Unit
	Jon Eric Angell	1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,22-45 and 48-54* is/are pending in the application.

4a) Of the above claim(s) *2-18,22-45 and 48-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Action is in response to the communication filed on 6/9/2005. The amendment filed 6/9/2005 is acknowledged. The amendment has been entered. Claims 1-18, 22-45, 48-54 are currently pending in the application and are addressed herein.

Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Europe (i.e., EPO 99306702.4) on 08/24/1999. It is noted, however, that a copy of the certified copy of the EPO 99306702.4 document has not been received by the Office in this National Stage application (PCT Rule 17.2(a)). Therefore, the instant application does not receive the benefit of priority to the filing date of the EPO 99306702.4 document. As such, the effective filing date of the instant application is considered to 8/21/2000, which is the filing date of the international application PCT/EP00/08182.

Election/Restrictions

Claims 2-18, 22-45 and 48-54 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention for the reasons of record (See

Office Action mailed on 12/7/04). Applicant timely traversed the restriction (election) requirement in the reply filed on 10/4/2004.

Claim 1 is examined herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims encompass (1) "a Gas1 protein capable of inducing apoptosis in a cell", as well as (2) "a lethal protein" that normally induces Gas1-mediated cell death wherein the lethal protein can be any one of: metabotropic glutamate receptors, ionotropic glutamate receptors, excitatory amino acid receptors, cytokine receptors, chemokine receptors, monoamine receptors, peptide receptors, kinases, and caspases.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

With respect to "a Gas1 protein capable of inducing apoptosis in a cell" it is noted that the claim does not set forth any structural limitations for the term "a Gas1 protein". Furthermore, the specification indicates that Gas1 proteins encompass functional equivalents, derivatives, and modified proteins, including fragments (e.g., see 14, lines 7-37). Therefore, the term "a Gas1 protein" is interpreted as encompassing a genus of proteins that includes an enormous number of different proteins, including proteins that are structurally distinct. The specification and prior art appear to describe just one member of the claimed genus: the protein which is disclosed as SEQ ID NO: 2.

With respect to the term "a lethal protein" the claim indicates that the lethal protein can be any one of: metabotropic glutamate receptors, ionotropic glutamate receptors, excitatory amino acid receptors, cytokine receptors, chemokine receptors, monoamine receptors, peptide receptors, kinases, and caspases, wherein the lethal protein normally induces Gas1-mediated cell death (See claim 1, step (c)). It is noted that metabotropic glutamate receptors, ionotropic glutamate receptors, excitatory amino acid receptors, cytokine receptors, chemokine receptors, monoamine receptors, peptide receptors, kinases, and caspases are all broad genera of biological molecules where each genus encompasses a myriad of structurally and functionally different molecules. Therefore, it is clear that not all species within each claimed genus would be capable of inducing Gas1-mediated cell death. Furthermore, neither the specification nor the prior art discloses which molecules within the each of the claimed genera of lethal proteins, "normally induces Gas1-mediated cell death" as required by the claim.

Accordingly, the specification does not provide adequate written description of the claimed genus of Gas1 proteins or for the genus of claimed lethal proteins.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the genus of molecules encompassed by the claims. Therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

To the extent that the claimed method is not described in the instant disclosure, claim 1 is also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

Response to Arguments

Applicant's arguments filed 6/9/2005 have been fully considered. With respect to the objection to the claim and the rejection of claim 1 under 35 USC 112, 2nd paragraph, Applicants arguments, in view of the amendment, are persuasive. With respect to the rejection of claim 1 under 35 USC 112, 1st paragraph, as it applies to the instant rejection, Applicants arguments are not persuasive.

Applicants argue that claim 1 has been amended such that it no longer recites functional equivalents, derivatives and bioprecursors. Applicants assert that the claim is directed to Gas1 polypeptides, and is adequately described as they were clearly in possession of the claimed method.

In response, it is respectfully pointed out that although the claim has been amended such that is does not explicitly recite Gas1 equivalents, derivatives and bioprecursors, the claim still encompasses variants of the disclosed Gas1 protein for the reasons indicated above. Therefore, the claim still encompasses variants of the disclosed Gas1 protein, but the specification has not provided an adequate written description of a representative number of species Gas1 variant proteins encompassed by the claims for the reasons indicated above. Therefore, Applicants arguments are not persuasive.

With respect to the genus of "lethal proteins" encompassed by the claims, Applicants argue that claim 1 has been amended such that it is limited to a specific group of proteins whose structures are well known in the art. The Applicants assert that they were clearly in possession of the nucleic acid sequences encoding such proteins to the extent they were known to skilled artisans at the time of filing, particularly where there was clearly established relationship

between structure and function for these well understood proteins. Applicants also contend that they need not disclose that which is well known.

In response, it is acknowledged that the general structure of metabotropic glutamate receptors, ionotropic glutamate receptors, excitatory amino acid receptors, cytokine receptors, chemokine receptors, monoamine receptors, peptide receptors, kinases, and caspases were known in the art. However, the claim is specifically limited to metabotropic glutamate receptors, ionotropic glutamate receptors, excitatory amino acid receptors, cytokine receptors, chemokine receptors, monoamine receptors, peptide receptors, kinases, and caspases that normally induce Gas1-mediated cell death (e.g., see claim 1, step (c)). As indicated above, metabotropic glutamate receptors, ionotropic glutamate receptors, excitatory amino acid receptors, cytokine receptors, chemokine receptors, monoamine receptors, peptide receptors, kinases, and caspases are all broad genera of biological molecules where each genus encompasses a myriad of structurally and functionally different molecules. Therefore, it is clear that not all species within each claimed genus would be capable of inducing Gas1-mediated cell death. For instance, certainly not all kinases would normally induce Gas1-mediated cell death. Furthermore, neither the specification nor the prior art discloses which molecules within the each of the claimed genera of lethal proteins, "normally induces Gas1-mediated cell death" as required by the claim. Therefore, Applicants arguments are not persuasive.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1635

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